

FORM PTO-1449/A and B (Modified)				APPLICATION NO.: 09/316,199		ATTY. DOCKET NO.: C1040.70006US00	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				FILING DATE: May 21, 1999		CONFIRMATION NO.: 7506	
				APPLICANT: McCluskie et al.			
				GROUP ART UNIT: 1632		EXAMINER: Dave Nguyen	
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#### U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
✓	A1	6,174,872		Carson et al.	01/16/2001
	A2	6,194,388		Krieg et al.	02/27/2001
	A3	6,207,646		Krieg et al.	03/27/2001
	A4	6,214,806		Krieg et al.	04/10/2001
	A5	6,218,371		Krieg et al.	04/17/2001
	A6	6,239,116		Krieg et al.	05/29/2001
	A7	6,339,068		Krieg et al.	01/15/2002
	A8	6,406,705		Davis et al.	06/18/2002
	A9	6,429,199		Krieg et al.	08/06/2002
	A10	6,514,948		Raz et al.	02/04/2003
	A11	6,562,798		Schwartz	05/13/2003
	A12	6,589,940		Raz et al.	07/08/2003
	A13	6,610,661		Carson et al.	08/26/2003
	A14	6,613,751		Raz et al.	09/02/2003


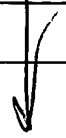
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Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD- YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
✓	/	US	20020055477A1		Nest et al.	05/09/2002	
	/	US	20020142978A1		Raz et al.	10/03/2002	
	/	US	20020156003A1		Bratzler et al.	10/24/2002	
	/	US	20030026782A1		Krieg et al.	02/06/2003	
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	/	US	20030050263A1		Krieg et al.	03/15/2003	
	/	US	20030078223A1		Raz et al.	04/24/2003	
	/	US	20030092663A1		Raz	05/15/2003	
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		WO	01/12223 A2		Dynavax	02/22/2001	

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**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	<del>C1</del>	Choi AH et al., "The level of protection against rotavirus shedding in mice following immunization with a chimeric VP6 protein is dependant on the route and the coadministered adjuvant", <i>Vaccine</i> . 2002 Mar 15;20(13-14): 1733-40.	
	<del>C2</del>	Davis, HL, "Use of CpG DNA for enhancing specific immune responses", <i>Curr Top Microbiol Immunol</i> . 2000; 247: 171-83.	
	<del>C3</del>	Dumais, N. et al., "Mucosal immunization with inactivated human immunodeficiency virus plus CpG oligodeoxynucleotides induce genital immune responses and protection against intravaginal challenge", <i>J. Infect. Dis</i> . 2002 Oct 15; 186(8):1098-105. Epub 2002 Sept.	
	<del>C4</del>	Gallichan, W. Scott et al., "Intranasal Immunization with CpG Oligodeoxynucleotides as an Adjuvant Dramatically Increases IgA and Protection Against Herpes Simplex Virus-2 in the Genital Tract", <i>The Journal of Immunology</i> , 2001, 166: 3451-3457.	
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	<del>C7</del>	Kovarik, J et al., "Adjuvant effect of CpG oligodeoxynucleotides on responses against T-independent type 2 antigens", <i>Immunology</i> . 2001 Jan; 102(1): 67-76..	
	<del>C8</del>	Krieg, AM et al., "Bacterial DNA or oligonucleotides containing CpG motifs protect mice from lethal <i>L. monocytogenes</i> challenge", Abstract from 1996 meeting on <i>Molecular Approaches to the Control of Infectious Diseases</i> , Cold Spring Harbor Laboratory, September 9-13, 1996. p.116.	
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	<del>C10</del>	Krieg, AM, "Immune Effects and mechanisms of action of CpG motifs", <i>Vaccine</i> . 2001 Nov. 8; 19(6): 618-22.	
	<del>C11</del>	Krieg, AM et al., "Enhancing vaccines with immune stimulatory CpG DNA", <i>Curr Opin Mol Ther</i> . 2001 Feb; 3(1):15-24	
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	<del>C13</del>	Malanchere-Bres, E et al., "CpG Oligodeoxynucleotides with Hepatitis B Surface Antigen (HBsAg) for Vaccination in HBsAg-Transgenic Mice", <i>Journal of Virology</i> , July 2001, p. 6482-6491	
	<del>C14</del>	Brazolot Millan, Cynthia L. et al., "CpG DNA can induce strong Th1 humoral and cell-mediated immune responses against hepatitis B surface antigen in young mice", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 95, pp. 15553-15558, December 1998 Immunology	
	<del>C15</del>	McCluskie, MJ et al., "Muscol immunization with DNA vaccines", <i>Microbes Infect</i> . 1999 Jul; 1(9): 685-98.	
	<del>C16</del>	McCluskie, MJ et al., "CpG DNA as mucosal adjuvant", <i>Vaccine</i> . 1999 Sep; 18(3-4): 231-7.	
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	<del>C19</del>	McCluskie, MJ et al., "Intranasal immunization of mice with CpG DNA induces strong systematic and mucosal responses that are influenced by other mucosal adjuvants and antigen distribution", <i>Mol Med</i> . 2000 Oct; 6(10): 867-77.	

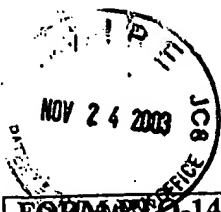
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Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C20	McCluskie, MJ et al., "Oral, intrarectal and intranasal immunizations using CpG and non-CpG oligodeoxynucleotides as adjuvants", <i>Vaccine</i> 19 (2001) 413-422	
	<del>C21</del>	McCluskie, MJ et al., "The potential of CpG oligodeoxynucleotides as muscol adjuvants", <i>Crit Rev Immunol</i> . 2001; 21(1-3): 103-20	
	<del>C22</del>	McCluskie, MJ et al., "The use of CpG DNA as mucosal vaccine adjuvant", <i>Curr Opin Investig Drugs</i> . 2001 Jan; 2(1): 35-9.	
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	<del>C24</del>	McCluskie, MJ et al., "Mucosal immunization of mice using CpG DNA and/or mutants of the heat-labile enterotoxin of Escherichia coli as adjuvants", <i>Vaccine</i> . 2001 Jun 14; 19(27): 3759-68.	
	<del>C25</del>	McCluskie, MJ et al., "Parenteral and mucosal prime-boost immunization strategies in mice with hepatitis B surface antigen and CpG DNA", <i>FEMS Immunol Med Microbiol</i> . 2002 Feb 18; 32(3): 179-85.	
	<del>C26</del>	Pal, S. et al., "Immunization with the Chlamydia trachomatis mouse pneumonitis major outer membrane protein by use of CpG oligodeoxynucleotides as an adjuvant induces a protective immune response against an intranasal chlaymdial challenge", <i>Infect Immun</i> . 2002 Sep; 70(9): 4812-7.	
	<del>C27</del>	Payette PJ et al., "History of vaccines and positioning of current trends", <i>Curr Drug Targets Infect Disord</i> . 2001 Nov; 1(3): 241-7.	
	<del>C28</del>	Sajic D et al., "Parameters of CpG oligodeoxynucleotide-induced protection against intravaginal HSV-2 challenge", <i>J Med Virol</i> . 2003 Dec; 71(4):561-568.	
	<del>C29</del>	Weeratna, RD et al., "CpG ODN allows lower doses of antigen against hepatitis B surface antigen in BALB/c mice", <i>Immunol Cell Biol</i> . 2003 Feb; 81(1): 59-62.	
	<del>C30</del>	Weeratna, RD et al., "CpG ODN can redirect the Th bias of established Th2 immune responses in adult and young mice", <i>FEMS Immunol Med Microbiol</i> . 2001 Dec; 32(1): 65-71.	
	<del>C31</del>	Weeratna, RD., "Priming of immune responses to hepatitis B surface antigen in young mice immunized in the presence of maternally derived antibodies", <i>FEMS Immunol Med Microbiol</i> . 2001 Apr; 30(3): 241-7.	
<del>C32</del>	Weeratna, RD, "CpG DNA induces stronger immune responses with less toxicity than other adjuvants", <i>Vaccine</i> . 2000 Mar 6; 18(17): 1755-62.		

EXAMINER	DATE CONSIDERED 2/19/04
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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FORM 1449 (Modified)	ATTY. DOCKET NO. C1040/7006	SERIAL NO. 09/316,199
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LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	APPLICANT McCluskie et al.	
	FILING DATE May 21, 1999	GROUP

U.S. PATENT DOCUMENTS

Exam Init	Ref Des	Document No.	Date	Name	Class	Sub Class	FILING DATE If Appropriate
Q	A1	3,906,092	09/16/75	Hilleman et al.			
	A2	5,248,670	09/28/93	Draper et al.	514	44	
	A3	5,585,479	12/17/96	Hoke et al.	536	24.5	
	A4	5,663,153	09/02/97	Hutcherson et al.	514	44	
	A5	5,786,189	07/28/98	Locht et al.	435	172.3	
	A6	5,849,719	12/15/98	Carson et al.	514	44	
	A7	5,723,335	03/03/98	Hutcherson, et al.	435	375	

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		Country & Doc. No. (11)	Pub. Date (43)		Class	Sub Class	Translation Yes	No
Q	B1	WO 91/12811	09/05/91	PCT	A61K	31/70		
	B2	0468520	01/29/92	EPO	A61K	31/70		
	B3	WO 92/03456	03/05/92	PCT	C07H	15/12		
	B4	WO 92/18522	10/29/92	PCT	C07H	21/00		
	B5	WO 92/21353	12/10/92	PCT	A61K	31/70		
	B6	0302758 B1	03/16/94	EPO	C12N	15/37		
	B7	WO 94/19945	09/15/94	PCT	A01N	43/04		
	B8	WO 95/05853	03/02/95	Regents of the University of CA				
	B9	WO 95/26204	10/95	PCT	A61K	48/00		
	B10	WO 96/02555	02/01/96	PCT				
	B11	WO 96/35782	11/14/96	Applied Research Systems				
	B12	WO 97/28259	08/07/97	PCT	C12N	15/00		
	B13	WO 98/18810	05/07/98	PCT	C07H	21/00		
	B14	WO 98/37919	09/03/98	PCT	A61K	49/00		
	B15	WO 98/40100	09/17/98	PCT	A61K	39/39		
	B16	WO 98/52581	11/26/98	PCT	A61K	35/00		
	B17	WO 98/14210	04/09/98	PCT	A61K	39/35		

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(Including Author, Title, Date, Pertinent Pages, Publication, Etc.)

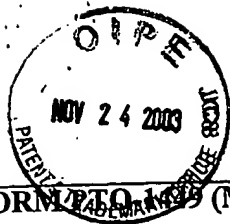
Q	C1	Adya N et al., Expansion of CREB's DNA recognition specificity by Tax results from interaction with Ala-Ala-Arg at positions 282-284 near the conserved DNA-binding domain of CREB. <i>Proc Natl Acad Sci USA</i> 91(12):5642-6, 7 Jun 1994.
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LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT		C1040/7006	09/316,199
		APPLICANT McCluskie et al.	
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<input checked="" type="checkbox"/>	C3	Azad RF et al., Antiviral Activity of a Phosphorothioate Oligonucleotide Complementary to RNA of the Human Cytomegalovirus Major Immediate-Early Region. <i>Antimicrobial Agents and Chemotherapy</i> , 37:1945-1954, September, 1993.	
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<input checked="" type="checkbox"/>	C5	Ballas ZK et al., Induction of NK activity in murine and human cells by CpG motifs in oligodeoxynucleotides and bacterial DNA. <i>J Immunol</i> 157(5):1840-5, 1996.	
<input checked="" type="checkbox"/>	C6	Bayever, E., Systemic Administration of a Phosphorothioate Oligonucleotide with a Sequence Complementary to p53 for Acute Myelogenous leukemia and Myelodysplastic Syndrome: Initial Results of a Phase I Trial, <i>Antisense Res. &amp; Dev.</i> (1993), 3:383-390.	
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<input checked="" type="checkbox"/>	C18	Chow Y et al., Improvement of Hepatitis B Virus DNA Vaccines by Plasmids Coexpressing Hepatitis B Surface Antigen and Interleukin-2, <i>Journal of Virology</i> , Vol. 71, No. 1, pp. 169-178, Jan. 1997.	
<input checked="" type="checkbox"/>	C19	Chow Y et al., Development of Th1 and Th2 Populations and the Nature of Immune Responses to Hepatitis B Virus DNA Vaccines Can Be Modulated by Codelivery of Various Cytokine Genes, <i>The Journal of Immunology</i> , 160:1320-1329, 1998.	
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		APPLICANT McCluskie et al.	
		FILING DATE May 21, 1999	GROUP
<input checked="" type="checkbox"/>	C25	Daeshia M et al., Immune induction and modulation by topical ocular administration of plasmid DNA encoding Antigens and cytokines, <i>Vaccine</i> , Vol. 16, No. 11/12, pp. 1103-1110, 1998.	
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<input type="checkbox"/>	C28	Erb KJ et al., Infection of mice with Mycobacterium bovis-Bacillus Calmette-Guerin (BCG) suppresses allergen-induced airway eosinophilia. <i>J Exp Med</i> 187(4):561-9, 16 Feb 1998.	
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<input type="checkbox"/>	C30	Fox RI, Mechanism of action of hydroxychloroquine as an antirheumatic drug. <i>Chemical Abstracts</i> , 120:15, Abstract No. 182630 (April 29, 1994).	
<input type="checkbox"/>	C31	Gordon et al., Safety, Immunogenicity, and Efficacy of a Recombinantly Produced <i>Plasmodium falciparum</i> Circumsporozoite Protein-Hepatitis B Surface Antigen Subunit Vaccine, <i>JID</i> , 171, pp. 1576-1585, June 1995.	
<input type="checkbox"/>	C32	Gura, T., Antisense Has Growing Pains. <i>Science</i> (1995), 270:575-576.	
<input type="checkbox"/>	C33	Hadden J et al., Immunostimulants. <i>TIPS</i> , (1993), 141:169-174.	
<input type="checkbox"/>	C34	Hadden J et al., Immunopharmacology, <i>JAMA</i> , (1992) 268:20:2964-2969.	
<input type="checkbox"/>	C35	Halpern MD et al., Bacterial DNA induces murine interferon-gamma production by stimulation of interleukin-12 and tumor necrosis factor-alpha. <i>Cell Immunol</i> 167(1):72-8, 1996.	
<input type="checkbox"/>	C36	Hatzfeld J., Release of Early Human Hematopoietic Progenitors from Quiescence by Antisense Transforming Growth Factor $\beta$ 1 or Rb Oligonucleotides, <i>J. Exp. Med.</i> , (1991) 174:925-929.	
<input type="checkbox"/>	C37	Heppner et al., Safety, Immunogenicity, and Efficacy of <i>Plasmodium falciparum</i> Repeatless Circumsporozoite Protein Vaccine Encapsulated in Liposomes, <i>JID</i> , 174, pp. 361-366, August 1996.	
<input type="checkbox"/>	C38	Highfield PE, Sepsis: the More, the Murkier. <i>Biotechnology</i> , 12:828, August 12, 1994.	
<input type="checkbox"/>	C39	Hoeffler JP et al., Identification of multiple nuclear factors that interact with cyclic adenosine 3',5'-monophosphate response element-binding protein and activating transcription factor-2 by protein-protein interactions. <i>Mol Endocrinol</i> 5(2):256-66, Feb 1991.	
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<input type="checkbox"/>	C41	Iguchi-Arigo SM and Shaffner W, CpG methylation of the cAMP-responsive enhancer/promoter sequence TGACGTCA abolishes specific factor binding as well as transcriptional activation. <i>Genes Dev</i> 3(5):612-9, May 1989.	
<input type="checkbox"/>	C42	Iverson, P., et al., "Pharmacokinetics of an Antisense Phosphorothioate Oligodeoxynucleotide against ree from Human Immunodeficiency Virus Type 1 in the Adult male Rhesus Monkey Following Single Injections and Continuous Infusion", <i>Antisense Research and Development</i> , (1994), 4:43-52.	
<input type="checkbox"/>	C43	Ishikawa R et al., IFN induction and associated changes in splenic leukocyte distribution. <i>J Immunol</i> 150(9):3713-27, 1 May 1993	
<input type="checkbox"/>	C46	Kim JJ et al., In Vivo Engineering of a Cellular Immune Response by Coadministration of IL-12 Expression Vector With a DNA Immunogen, <i>The Journal of Immunology</i> , 158:816-826, 1997.	
<input type="checkbox"/>	C47	Kimura Y et al., Binding of Oligoguanilate to Scavenger Receptors Is Required for Oligonucleotides to Augment NK Cell Activity and Induce IFN, <i>J. Biochem.</i> , Vol. 116, 5:991-994, 1994.	
<input type="checkbox"/>	C48	Kline JN et al., CpG motif oligonucleotides are effective in prevention of eosinophilic inflammation in a murine model of asthma. <i>J Invest Med</i> 44(7):380A, 1996.	
<input checked="" type="checkbox"/>	C49	Kline JN et al., Immune redirection by CpG oligonucleotides. Conversion of a Th2 response to a Th1 response in a murine model of asthma. <i>J Invest Med</i> 45(3):282A, 1997.	

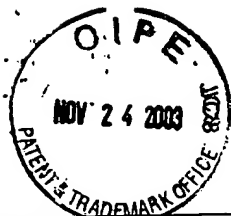
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LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT		C1040/7006	09/316,199
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		FILING DATE May 21, 1999	GROUP
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	C54	Krieg AM et al., Uptake of oligodeoxyribonucleotides by lymphoid cells is heterogeneous and inducible. <i>Antisense Res Dev</i> 1(2):161-71, Summer 1991.	
	C55	Krieg AM et al., Oligodeoxynucleotide modifications determine the magnitude of B cell stimulation by CpG motifs. <i>Antisense Nucleic Acid Drug Dev</i> 6(2):133-9, Summer 1996.	
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	C58	Krieg AM et al., "Phosphorothioate Oligodeoxynucleotides: Antisense or Anti-Protein?", <i>Antisense Research and Development</i> , (1995), 5:241	
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	C61	Krieg AM et al., "The role of CpG dinucleotides in DNA vaccines", <i>Trends in Microbiology</i> , Vol. 6, pp. 23-27, Jan 1998.	
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	C65	Larsen DL et al., Coadministration of DNA Encoding Interleukin-6 and Hemagglutinin Confers Protection from Influenza Virus Challenge in Mice, <i>Journal of Virology</i> , Vol. 72, No. 2, pp. 1704-1708, Feb. 1998.	
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FORM PTO-1449 (Modified)		ATTY. DOCKET NO.  C1040/7006	SERIAL NO.  09/316,199
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT			
		APPLICANT McCluskie et al.	
		FILING DATE May 21, 1999	GROUP
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	C82	Mottram et al., A novel CDC2-related protein kinase from leishmania mexicana LmmCRK1 is post-translationally regulated during the life cycle. <i>J. Biol. Chem.</i> 268:28, 21044-21052 (October 1993).	
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	C87	Pisetsky et al., Stimulation of Murine Lymphocyte Proliferation... Simplex Virus., <i>Life Science</i> , 54:101-107, (1994)	
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	C95	Schnell et al., Identification and characterization of a <i>Saccharomyces cerevisiae</i> gene (PAR1) conferring resistance to iron chelators. <i>Eur. J. Biochem.</i> , 200:487-493.	
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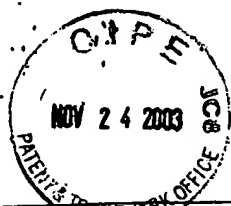
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		APPLICANT McCluskie et al.	
		FILING DATE May 21, 1999	GROUP
DM	C97	Schwartz DA et al., Endotoxin responsiveness and grain dust-induced inflammation in the lower respiratory tract. <i>Am J Physiol</i> 267(5 Pt 1):L609-17, 1994.	
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LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT		C1040/7006	09/316,199
APPLICANT McCluskie et al.			
		FILING DATE May 21, 1999	GROUP
✓	C118	Vosika G et al., Phase I Study of Intravenous Mycobacterial Cell Wall Skeleton and Trehalose Cimycolate Attached To Oil Droplets, <i>Journal of Biological Response Modifiers</i> , 3:620-626, 1984.	
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	C135	Yamamoto T et al., Synthetic Oligonucleotides with Certain Palindromes Stimulate Interferon Production of Human Peripheral Blood Lymphocytes <i>in vitro</i> . <i>Jpn. J. Cancer Res.</i> , 85:775-779, 1994.	
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